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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

029714-00017

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on _____

Signature _____

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name _____

Application Number

10/783,362

Filed

February 20, 2004

First Named Inventor

Shipping WANG et al.

Art Unit

1615

Examiner

Hasan S. AHMED

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 44,751
☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



Signature

Dawn C. Russell

Typed or printed name

202-857-6000

Telephone number

February 1, 2011

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-----------------------------------|---------------------------------|
| In re the Application of: | Confirmation No.: 2424 |
| Shiping WANG et al. | Art Unit: 1615 |
| Application No.: 10/783,362 | Examiner: Hasan S. Ahmed |
| Filed: February 20, 2004 | Attorney Dkt. No.: 029714-00017 |
| For: ANTIMICROBIAL MEDICAL GLOVES | |

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Date: February 1, 2011

Sir:

In response to the Final Office Action mailed September 2, 2010, Applicants respectfully submit that the Office Action is both factually and legally incorrect, and hereby submit this Pre-Appeal Brief Request for Review. This request is not accompanied by an amendment to the currently pending claims, and is being filed with a Notice of Appeal.

Claims 7-29, 33-34, 43-46, and 48-49 are pending in this application, with claims 7-26 having been withdrawn as being directed to a non-elected invention. Claims 27-29, 33-34, 43-46 and 48-49 are currently under consideration, and claims 27 and 43 are the independent claims under consideration. The outstanding Office Action is the sixth Office Action in this application. This application qualifies for Appeal.

Essential Elements are Not Disclosed by the Cited References

Claims 27-31, 33-34, 43-46, 48-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman") and U.S. Patent No. 5,357,636 ("Dresdner"). This rejection was originally

set forth in the October 1, 2009 Office Action. Applicants respectfully traverse the outstanding rejection, and submit that it has been made in error for at least the reasons set forth below.

Applicants respectfully submit that the combination of Modak, Dresdner, McDevitt, and Schichman fails to disclose or suggest the presently-claimed invention, which is directed to a packaged antimicrobial elastomeric article that is **essentially free of powder and starch**, and is **coated on an outside surface with at least one antimicrobial agent**.

Modak relates to an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid. See col. 2, lines 20-22. A suitable lubricating agent may include powders such as zinc oxide, hydroxycellulose, or corn starch that has been blocked with benzalkonium chloride, didecyldimethylammonium chloride, or gluconic acid. See col. 2, lines 20-22 and 51-63. When corn starch is used, the corn starch is blocked in order to prevent the anti-infective agent from being adsorbed. The biguanide anti-infective agent is specifically provided inside the glove in order to protect health care workers from exposure to pathogens, such as HIV and HBV. See col. 1, lines 32-40.

Each embodiment and example described in Modak requires that the glove be coated with a slurry containing a non-adsorbent lubricating agent (i.e., a starch or powder), and an antiviral agent. See Example 1 (slurry containing 15% cornstarch and 2% CHG), Example 2 (slurry containing 15% cornstarch and 2% CHG), Example 3 (slurry containing 5% zinc oxide powder and 1-2% CHG), Example 4 (2% hydroxyethylcellulose, optionally 1% zinc oxide powder, and 1-2% CHG), and Example 7 (8% cornstarch and 2% CHG). Even the comparative examples set forth from col. 5, line 55 to col. 6, line 60 are based on preparing gloves using slurry dip coatings containing starch and CHG. All of the slurries described in Modak contain starch or powder lubricants such as cornstarch, hydroxyethylcellulose, and zinc oxide. There is

no disclosure or suggestion in Modak of gloves having antiviral coatings that are essentially free of powder and starch.

The Office Action took the position that Example 4 of Modak discloses a slurry of 2% hydroxyethylcellulose and 1-2% CHG. The Office Action calculated that a slurry containing 2% hydroxyethylcellulose would contain 0.002 mg of hydroxyethylcellulose, and that therefore less than 2 grams of hydroxyethylcellulose would necessarily be deposited on the glove, thereby disclosing the feature that the elastomeric article is “essentially free” of powder and starch. However, the math used to arrive at this conclusion is erroneous. Assuming that the slurry is formed in 1 liter of water (as was assumed in the Office Action), then 1 liter of water is equivalent to 1 kg or 1000 mg of water. It is clear that 2% of 1000 mg is 20 mg, not 0.002 mg. More than enough hydroxyethylcellulose would be present in such a hydroxyethylcellulose slurry to form a coating of at least 2 mg of hydroxyethylcellulose on a glove.

The Office Action admits that Modak does not disclose a glove that has an outer coating of anti-infective agent, but cites Dresdner for this feature. Applicants disagree with the assertion that Dresdner remedies this deficiency.

Dresdner is directed to medical gloves that include a non-liquid antiseptic composition provided ***between*** inner and outer elastomeric layers of a glove, so that the antiseptic composition can protect the hand of the wearer from infections if the glove is punctured. See Abstract and Figure 2A. Applicants submit that one skilled in the art would not modify the glove of Modak, which has an inner antiseptic coating, to provide an outer antiseptic coating thereon based on the disclosure of Dresdner. Like Modak, the primary goal of Dresdner is to protect the hands of the person wearing the glove, not prevention of cross-contamination. Further, one skilled in the art would recognize that the antiseptic composition of Dresdner that is sandwiched between glove layers would not be suitable for use on the outside surface of an elastomeric article.

The Office Action alleges that Dresdner discloses that “the outer surface of the inner layer of the glove (e.g., the outside surface of item (2) of Fig. 1B) meets the instant

specification's definition of 'outer surface' since this surface comes into contact with other objects, such as medical instruments (see, e.g., col. 19, lines 59-67 and Fig 2A and 2B) and does not contact the wearer's skin." The Office Action then indicates that the instant claims do not preclude the extra layer that covers the antiseptic composition. ***This interpretation of Dresdner and the meaning of the term "outer surface" is improper because it is so broad as to render the term "outer surface" meaningless and effectively remove it from the claim.*** Although the PTO is permitted to give claim terms their "broadest reasonable interpretation consistent with the specification," this must be consistent with the interpretation that those skilled in the art would reach. See MPEP 2111, citing *In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999)

The definition of the claim term "outer surface" set forth in the specification is as follows:

"[A] preferred embodiment according to the invention is prepared by applying the antimicrobial coating composition to the outer surface of a medical or industrial glove to minimize or reduce cross-contamination as a result of multiple contacts. By outside surface is meant the portion of the glove that comes into contact with other objects such as patients, medical instruments, table tops, or counters." See page 11.

One skilled in the art would not interpret an outer coating that may be used to reduce cross-contamination between patients, instruments, table tops, and counters to encompass the inner coating of Dresdner, which is sandwiched between elastomeric layers and is only released when the elastomeric layers are punctured. The claim construction advanced in the Office Action is erroneous. One skilled in the art would not look to Dresdner for guidance to prepare an essentially starch and powder-free elastomeric article having an antimicrobial coating on an outer surface.

These deficiencies are not remedied by McDevitt and/or Shichman.

McDevitt merely discloses a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. Shichman merely discloses packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. They do not disclose elastomeric

articles that are essentially free of powder and starch that are coated on an outside surface with at least one antimicrobial agent.

In view of the remarks presented above, Applicants respectfully submit that the combination of Modak, Dresdner, McDevitt, and Shichman fails to disclose or suggest the invention set forth in claims 27-29, 33-34, 43-46 and 48-49, and respectfully request that this rejection be withdrawn.

Conclusion

For all of the above reasons, a favorable decision and allowance of all pending claims are earnestly solicited.

In the event this paper is not considered to be timely filed, Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 029714.00017.**

Respectfully submitted,



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Enclosures: Notice of Appeal (Form PTO/SB/31)
Pre-Appeal Brief Request for Review (Form PTO/SB/33)